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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,310

05/12/2006

Jorgen Carlsson

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02/24/2011

WIGGIN AND DANA LLP
ATTENTION: PATENT DOCKETING
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EXAMINER

SWARTZ, RODNEY P

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,310	Applicant(s) CARLSSON ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,7,10,11,14-33,35-41,47,49,52-54,56 and 58-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 and 20 is/are allowed.
- 6) ☒ Claim(s) 1-3,7,10,11,14-18,21-33,35-41,47,49,52-54,56 and 58-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants' Response to Office Action, received 9 December 2010, is acknowledged. Claims 1, 7, 18 and 19 have been amended. Claims 8, 9, 12 and 13 have been cancelled. New claim 60 has been added.
2. Claims 1-3, 7, 10, 11, 14-33, 35-41, 47, 49, 52-54, 56 and 58-60 are pending and under consideration.

Rejections Withdrawn or Moot

3. The rejection of claim 12 under 35 U.S.C. 102(b) as being anticipated by Nilsson et al (WO95/19374, 20July1995), is moot in light of the cancellation of the claim.
4. The rejection of claims 8, 9 and 13 under 35 U.S.C. 112, second paragraph, is moot in light of the cancellation of the claims.
5. The rejection of claims 15, 18-20, 24-33, 35-41, 47, 49, 52-54, 56, 58 and 59 under 35 U.S.C. 112, second paragraph, is withdrawn.
6. The rejection of claims 1-3, 7, 10, 11, 14, 16, 17, 21-23 and 25 under 35 U.S.C. 102(b) as being anticipated by Nilsson et al (WO95/19374, 20July1995), is

Applicants argue that the claims as newly amended, list specific combinations of mutations that are not disclosed or suggested by Nilsson et al.

The examiner has considered applicants' arguments, in light of the amendments of the claims, and finds it persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Originally, claim 1 was drawn to a polypeptide which "comprises" SEQ ID NO:1, having from 4 to about 20 substitution mutations thereon, comprising ≥ 4 substitution mutations at the positions 13, 14, 28, 32 and 35. In this embodiment, the numbering of positions could be based upon either the sequence of the claimed polypeptide or on the sequence of SEQ ID NO:1.

However, the new amendment of claim 1 restricts the substitution to specific pairs, i.e., F to Y at position 13, Y to W a position 14, Q to R at position 32, and K to Y at position 35. The claim does not state that these specific mutations depend solely on the numbering of SEQ ID NO:1. Thus, it is unclear if the numbering is based solely on the numbering of SEQ ID NO:1 or on the numbering of the unknown sequence of the claimed polypeptide which "comprises" SEQ ID NO:1.

Claims 2, 3, 7, 10, 11, 14-18, 21-33, 35-41, 47, 49, 52-54, 56 and 58-60 depend from claim 1, but do not clarify the issue.

Conclusion

8. Claims 1-3, 7, 10, 11, 14-18, 21-33, 35-41, 47, 49, 52-54, 56 and 58-60 are rejected.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of

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the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Larry Helms, at (571)272-0832.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

February 24, 2011